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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,318	03/31/2004	Ron Wortley	11984.6	5172

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/814,318

Applicant(s)

WORTLEY ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to Applicant's amendment filed on 13 October 2006.

Drawings

1. The drawings were received on 13 October 2006. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (US Patent Application 2002/0099327).**
4. Regarding Claim 1 and 5, Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20).
5. Regarding Claims 2, 3, 6, and 7, Wilson'327 discloses a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (26a, 28a).
6. Regarding Claims 4 and 8, Wilson'327 shows that the difference in the lengths of the shaft members (14, 16) is up to 20 percent (Figure 1).

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7. Regarding Claim 9, Wilson'327 discloses a shaft (12) that is removably connected to tip (20).
8. Regarding Claim 10, Wilson'327 discloses a sheath (34) that covers the portion of the shaft (12) and the tip (20) that are connected.
9. Regarding Claims 11 and 12, sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (26a, 28a) exist on shaft (21).
10. Regarding Claim 13, the retaining ring inside sheath (34) compliments protrusions (26a, 28a) on shaft (12) (paragraph [0029]).
11. Regarding Claim 14, the retaining ring inside sheath (34) compliments protrusions (26a, 28a) on shaft (12) (paragraph [0029]).
12. Regarding Claim 15, Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20). Shaft (12) is removably connected to tip (20) and sheath (34) covers the portion of the tip (20) and shaft (12) that are connected.
13. Regarding Claim 16, Wilson'327 discloses that a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (21a) located on the outside of shaft members (14, 16).
14. Regarding Claims 17 and 18, sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring

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for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (21a) exist on shaft (21).

15. Regarding Claim 19, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

16. Regarding Claim 20, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. **Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran (US Patent 5,964,796) and Vardi, et al. (WO 02/076333).**

20. Imran'796 teaches the use of a multi-lumen catheter (11) with a multi-lumen tunneler (12). The tunneler (12) contains a tip (12) with a gripping means (21) and a

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plurality of flexible shaft members (26). Imran'796 does not teach a multi-lumen tunneler in which the shafts have different lengths.

21. Vardi'333 teaches an introducer in which the shaft members have different lengths (Figure 5 and page 8, lines 3-8) so that the introducer can be used for accessing a bifurcated vessel (page 6, lines 1-12). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Imran'796 with introducer shaft members having different lengths in order to create simultaneous access to the two vessels in a bifurcated vessel.

Response to Arguments

22. Claims 1-20: Applicant's arguments filed 13 October 2006 have been fully considered but they are not persuasive.

23. In response to applicant's argument that the device taught by Wilson'327 is catheter not a tunneler and therefore does not meet the requirements of 35 USC 102(b), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As shown in the above rejection, Wilson'327 meets all the structural limitations of Applicant's claims.

24. Applicant's arguments, see Amendment, filed 13 October 2006, with respect to the rejection(s) of claim(s) 21 under 35 USC 103(a) have been fully considered and are

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persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Imran (US Patent 5,964,796) and Vardi, et al. (WO 02/076333). See rejection above.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Durand, et al. (US Patent 5,405,329), Melker, et al. (US Patent 5,328,480).

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER